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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,829	07/29/2009	Steven D. Kimmell	17683 US PCT (AP)	5234
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ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599				
EXAMINER				
BOGWORTH, KAMI A				
ART UNIT		PAPER NUMBER		
3767				
NOTIFICATION DATE		DELIVERY MODE		
05/24/2012		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents_ip@allergan.com

Office Action Summary

Application No.

10/599,829

Applicant(s)

KIMMELL ET AL.

Examiner

KAMI A. BOSWORTH

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 51-62 is/are pending in the application.
- 5a) Of the above claim(s) 52-62 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 51 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 18 April 2012 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CIB) Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Drawings

1. The drawings were received on 4/18/2012. These drawings are not acceptable. Although the amendments to the drawings and the amendments to the specification corrected most of the deficiencies, the drawings remain objected to as failing to comply with 37 CFR 1.84(p)(5) because they still do not include the following reference sign mentioned in the description: containment element 228. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gartstein et al. (PG PUB 2004/0087992) in view of Fishman et al. (US Pat 5,139,029).
4. Re claim 51, Gartstein et al. disclose a multi-site injection system (Fig 49-50) comprising: a rotatable drum 781 (Fig 49,50) having an outer surface (as seen in Fig 49,50) with microprotrusions 787 (Fig 49,50) thereon, said microprotrusions having lumens 788 (Fig 49) therethrough for enabling transport of a medicament therethrough from an inner surface (as seen in Fig 49,50) of said rotatable drum and into a stratum corneum of a user (Para 222,223); a fixed inner drum 782 (Fig 49,50) for supporting said rotatable drum and having at least one radial opening 757 (Fig 49,50) therein for providing said medicament to the microprotrusion lumens (Para 223); a supply of said medicament disposed within the inner drum (in reservoir 759, Fig 50; Para 222,223); and a support 786 (Fig 50) for supporting the rotatable drum and the inner drum (Para 218) and for exposing an arcuate portion of said rotatable drum in order to enable rotation of said rotatable drum by rolling said rotatable drum against a user's skin (Para 223). Gartstein et al. disclose that the device could have two supports connected to a handle (Para 218) but does not explicitly disclose that these components form a housing with an opening for exposing the arcuate portion of the rotatable drum. Fishman et al., however, teach a multi-site injection system 300 (Fig 27-30) comprising a housing 304 (Fig 27-30) for supporting a rotatable drum 314 (Fig 28-30) with microprotrusions 316 (Fig 28-30) formed thereon, said housing having an opening (as seen in Fig 27-30) for exposing an arcuate portion of said rotatable drum in order to enable rotation of said rotatable drum by rolling said rotatable drum against a user's skin

(Col 11, Lines 30-34) for the purpose of enclosing the drum so that it may be rolled along the skin of the patient in a manner that the microprotrusions facing the skin pierce the skin while those that do not face the skin are shielded from the user/patient (as seen in Fig 30; Col 11, Lines 30-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gartstein et al. to include a housing with an opening formed therein, as taught by Fishman et al., for the purpose of enclosing the drum so that it may be rolled along the skin of the patient in a manner that the microprotrusions facing the skin pierce the skin while those that do not face the skin are shielded from the user/patient (as seen in Fig 30; Col 11, Lines 30-34). Further, Gartstein et al. does not disclose that the rotatable drug includes a sponge-like material for distributing the medicament. Fishman et al., however, also teaches a sponge-like material 320 (Fig 28-30; "foam rubber", as recited in Line 47 of Column 11, is a spongy rubber by definition; see the attached references from the American Heritage Dictionary and Encyclopedia Britannica) on the rotatable drum 314 (Fig 28-30) for distributing the medicament (since it is surrounds the microprotrusions 316 and only allows them to pierce the skin when compressed, it aids in distributing the medicament; Col 11, Lines 59-68) for the purpose of controlling the ability of the microprotrusions to pierce the skin (Col 11, Line 59 – Col 12, Line 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gartstein et al. to include a sponge-like material on the rotatable drum, as taught by Fishman et al., for the purpose of controlling the ability of the microprotrusions to pierce the skin (Col 11, Line 59 – Col 12, Line 7).

Response to Arguments

5. Applicant's arguments with respect to claim 51 have been considered but are moot in view of the present rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 8:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAMI A BOSWORTH/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767